

<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>		ATTORNEY'S DOCKET NUMBER <b>532552000102</b>
INTERNATIONAL APPLICATION NO. PCT/US2004/011812	INTERNATIONAL FILING DATE 16 April 2004	U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <b>107545243</b> Not Yet Assigned
TITLE OF INVENTION COMPOSITIONS FOR DELIVERY OF DRUG COMBINATIONS		PRIORITY DATE CLAIMED 16 April 2003
APPLICANT(S) FOR DO/EO/US Paul TARDI et al.		

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

- ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
- ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
- ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
- ☒ The US has been elected (Article 31).
- ☒ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
  - ☐ is attached hereto (required only if not communicated by the International Bureau).
  - ☐ has been communicated by the International Bureau.
  - ☒ is not required, as the application was filed in the United States Receiving Office (RO/US).
- ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - ☐ is attached hereto.
  - ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
- ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - ☐ are attached hereto (required only if not communicated by the International Bureau).
  - ☐ have been communicated by the International Bureau.
  - ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - ☒ have not been made and will not be made.
- ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
- ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
- ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

**Items 11 to 20 below concern document(s) or information included:**

- ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
- ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
- ☒ A preliminary amendment (10 pages)
- ☒ An Application Data Sheet under 37 CFR 1.76 (4 pages)
- ☐ A substitute specification.
- ☐ A power of attorney and/or change of address letter.
- ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 – 1.825.
- ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
- ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>10/553373</b> U.S. APPLICATION NO. (If known, see 37 CFR 1.5) Not Yet Assigned		INTERNATIONAL APPLICATION NO. PCT/US2004/011812		ATTORNEY'S DOCKET NUMBER 532552000102	
20. <input checked="" type="checkbox"/> Other items or information: Copy of the Published Application WO 2004/093795 (111 pages) Copy of International Search Report (3 pages) Copy of Response to First Written Opinion (17 pages) Return Receipt Postcard					
The following fees have been submitted				CALCULATIONS	PTO USE ONLY
21. <input checked="" type="checkbox"/> Basic national fee (37 CFR 1.492(a)) ..... \$300				\$ 300.00	
22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... \$0 All other situations ..... \$200				\$ 200.00	
23. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority ..... \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB ..... \$400 All other situations ..... \$500				\$ 100.00	
<b>TOTAL OF 21, 22 and 23 =</b>				\$ 600.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
111 - 100 =	11	1	x \$250.00	\$ 250.00	
Surcharge of \$130 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	24 - 20 =	4	x 50.00	200.00	
Independent claims	2 - 3 =	0	x	0.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+		
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$ 1,050.00	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.				525.00	
<b>SUBTOTAL =</b>				\$ 525.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				\$	
<b>TOTAL NATIONAL FEE =</b>				\$ 725.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$	
<b>TOTAL FEES ENCLOSED =</b>				\$ 725.00	
				Amount to be refunded:	\$
				Amount to be charged	\$

JC20 Rec'd PCT/PTO 17 OCT 2005

- a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 03-1952 in the amount of \$ 525.00 to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 03-1952. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038

**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Kate H. Murashige  
MORRISON & FOERSTER LLP  
3811 Valley Centre Drive  
Suite 500  
San Diego, California 92130-2332  
(858) 720-5112

*Kate H. Murashige*  
SIGNATURE

Kate H. Murashige  
NAME

29,959  
REGISTRATION NUMBER

CUSTOMER NUMBER: 25225

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)  
Not Yet Assigned

INTERNATIONAL APPLICATION NO.  
PCT/US2004/011812

ATTORNEY'S DOCKET NUMBER  
532552000102

**CERTIFICATE OF MAILING BY "EXPRESS MAIL"**

Express Mail Label No.: EV 272143786 US

Date of Deposit: October 17, 2005

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

10/17/05  
Date

*Marian L. Christopher*  
Marian L. Christopher